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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,283	09/27/2000	John A. Giordano	22920.0003	6590

23767 7590 05/06/2004

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/671,283	GIORDANO ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *155-170* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *155-170* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 15, 2004 has been entered.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 155-170 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to a composition free of chromium or free of added chromium. The claimed composition lacks support from the specification or the claims as original filed. Particularly, all the compositions disclosed in the specification comprise chromium, see, particularly pages 3, 10 and 11, and claims 1-116 in the specification. Therefore, the claimed subject matter herein was not described in the specification.

Claim Rejections 35 U.S.C.§ 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 155, 156, 158-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568).

3. Riley teaches an supplemental nutrient oral daily dosage composition comprising about 0.7 to about 15 mg Vitamin B1, about 0.7 to about 15 mg of vitamin B2, about 2 to 100 mg vitamin B6, about 6 to about 100 mg niacin, about 50 to about 800 mcg foliate (in the form of folic acid), about 4 to about 50 mg of pantothenic acid (in the for of d-calcium pantothenate), about 0.5 to about 40 mcg vitamin B12, about 5 to about 300 mcg biotin, about 5 to about 30 mg of zinc, about 10 to about 200 mcg selenium (in the form of L-selenomethionine), about 10 to about 300 mcg chromium, about 20 to about 1,000 mg vitamin C, about 5 to about 2,000 mg vitamin E. See, particularly, claim 1 and tables 2 and 3.

4. Riley does not teach expressly a composition consisting of the ingredients above.

However, it would have been prima facie obvious to one of ordinary skill in the art, at the time the claimed invention was made to make a composition consisting of the above nutritional components because each of the ingredients are known nutritional agents to human. It is prima facie obvious to combine two or more agents each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art;

thus, the claimed invention which is a combination of several known nutritional agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

5. Claims 162, 164, 166-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128).

6. Riley teaches an supplemental nutrient oral daily dosage composition comprising about 0.7 to about 15 mg Vitamin B1, about 0.7 to about 15 mg of vitamin B2, about 2 to 100 mg vitamin B6, about 6 to about 100 mg niacin, about 50 to about 800 mcg foliate (in the form of folic acid), about 4 to about 50 mg of pantothenic acid (in the for of d-calcium pantothenate), about 0.5 to about 40 mcg vitamin B12, about 5 to about 300 mcg biotin, about 5 to about 30 mg of zinc, about 10 to about 200 mcg selenium (in the form of L-selenomethionine), about 10 to about 300 mcg chromium, about 20 to about 1,000 mg vitamin C, about 5 to about 2,000 mg vitamin E. See, particularly, claim 1 and tables 2 and 3.

Riley does not teach expressly a composition without added chromium, or the particular amounts of folic acid.

7. However, Wakat teaches that for supplemental purpose, folic acid may be employed in the range of 0.35 mg to 10 mg. See, particularly, claims 1-3.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the amount of folic acid herein in an oral dosage form.

A person of ordinary skill in the art would have been motivated to employ more than 800 mcg of folic acid in an oral dosage form because folic acid are known to be supplemented up to 10 mg. Further, optimization of the amounts of active ingredients in a nutrient or therapeutical

composition is within the skill of the artisan, especially within a known range. Such optimization is considered to be an optimization of a result effective parameter, which is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. With respect to the limitation of "without addedchromium," note it would have been prima facie obvious to one of ordinary skill in the art, at the time the claimed invention was made to make a composition consisting of the above nutritional components because each of the ingredients are known nutritional agents to human. It is prima facie obvious to combine two or more agents each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of several known nutritional agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

8. Claim 157and 165 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128), for reasons set forth above, and in further view of Anderson (US 5,278,329).

9. Riley and Wakat do not teach expressly the particular zinc salts herein. However, Anderson teaches that zinc L-methionine is a known chromium salt useful as zinc supplements. See particularly, the abstract, column 1, line 5 bridging column 2, line 20, and the claims. One of ordinary skill in the art would have been motivated to employ any known zinc salt (e.g., L-methionine) in the composition of Riley because a skilled artisan possessing a pharmaceutical active, also possesses the salts, acids and esters of the said active. Employing of a known salt, acid, and ester of a known compound in lieu of the compound itself is within the skill of the

artisan. Moreover, the skilled artisan would expected the salts, acids esters of a known compound to exhibit therapeutical effects similar to those of the compounds itself.

Response to the Arguments

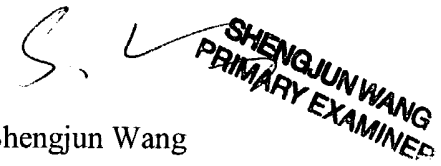
Applicant' amendments and remarks submitted November 13, 2003 and February 11, 2004 have been fully considered, but are not persuasive.

As stated in the advisory action mailed December 5, 2003, "Riley does teaches some specific relationship between nutrient, such as vitamin C to iron, vitamin D to calcium, but Riley never specifically teaches the criticality of the amounts of folic acid disclosed therein. Riley stats "the dosage of one nutrient, if not physiologically appropriate, may change the requirement of another nutrient and even impair the immune response." As shown by Wakat, more than .8 mg of folic acid is physiological appropriate. Therefore, considering the cited references as a whole, the claimed invention is obvious." Further, Question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. As exemplified in Raliy, vitamins and minerals are old and well-known nutritional ingredients found in founds, and they have been used as nutritional or food supplemental agents, either individually, or in combination. The instant claimed subject matter provides nothing more than a nutritional combination of various known vitamins and mineral. Absent evidence of unexpected benefit residing in the claimed combination, the claims are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Shengjun Wang

April 29, 2004